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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ELI LILLY & COMPANY, and COLUCID PHARMACEUTICALS, INC., Plaintiffs, v. QILU PHARMACEUTICAL CO., LTD., and QILU PHARMA INC., Defendants.	Civil Action No. _____ ***Highly Confidential*** ***Electronically Filed Under Seal***

COMPLAINT

Plaintiffs Eli Lilly & Co. and CoLucid Pharmaceuticals, Inc. (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants Qilu Pharmaceutical Co., Ltd. and Qilu Pharma Inc. (collectively, "Defendants"), hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendants' submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Plaintiffs'

REYVOW® (lasmiditan) tablets prior to the expiration of United States Patent No. 12,257,246.

THE PARTIES

2. Plaintiff Eli Lilly & Company ("Lilly") is a corporation organized and existing under the laws of the State of Indiana, having a principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

3. Plaintiff CoLucid Pharmaceuticals, Inc. ("CoLucid") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. CoLucid is a wholly owned subsidiary of Lilly.

4. Lilly and CoLucid are collectively referred to herein as "Plaintiffs."

5. On information and belief, Defendant Qilu Pharmaceutical Co., Ltd ("Qilu Ltd.") is a corporation organized and existing under the laws of China, having a principal place of business at 8888 Lvyou Road, High-Tech Zone, Jinan, 250104, China.

6. On information and belief, Defendant Qilu Pharma, Inc. ("Qilu Inc.") is a corporation organized and existing under the laws of the State of Pennsylvania, having a principal place of business at 101 Lindenwood Drive, Suite 225, Malvern, PA 19355.

7. Qilu Ltd. and Qilu Inc. are collectively referred to herein as "Qilu" or "Defendants."

8. On information and belief, Qilu Ltd. is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, including distributing, selling, and marketing generic drugs throughout the United States, including within the State of New Jersey, through its own actions and through the actions of its partners, agents, and subsidiaries, including U.S. agent Qilu Inc., from which Qilu Ltd. derives a substantial portion of its revenue.

9. On information and belief, Qilu Ltd. is listed as the applicant of ANDA No. 219350 (the "Qilu ANDA") and has sent notice to Lilly stating that Qilu Ltd. included a certification in the

Qilu ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

10. On information and belief, Qilu Inc. is the U.S. agent for Qilu Ltd. in connection with Qilu's ANDA.

11. On information and belief, Qilu Inc. acted in concert with Qilu Ltd. to prepare and submit the Qilu ANDA for Qilu's 50 mg and 100 mg tablets ("Qilu ANDA Products"), which was done at the direction and control of, and for the direct benefit of, Qilu Ltd.

12. On information and belief, following FDA approval of the Qilu ANDA, Qilu, through its own actions and through the actions of its partners, agents and subsidiaries, including Qilu Inc., will manufacture, supply, market, and sell the approved generic products throughout the United States, including New Jersey.

JURISDICTION AND VENUE

13. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*., generally, and 35 U.S.C. § 271(e)(2), specifically, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

14. Venue is proper in this Court as to Qilu Ltd. because, among other things, Qilu Ltd. is a foreign corporation not residing in any United States district and may be sued in any judicial district. 28 U.S.C. § 1391(b), (c); *see also* 28 U.S.C. § 1400(b).

15. Qilu Ltd. has been sued in this district previously in Hatch-Waxman patent infringement disputes and has not contested personal jurisdiction or venue in one or more cases. *See, e.g.*, *Boehringer Ingelheim Pharms. Inc. v. Qilu Pharm. Co. Ltd., et al.*, No. 3:21-cv-01732 (D.N.J.); *Helsinn Healthcare S.A. et al. v. Qilu Pharm. Co., Ltd. et al.*, No. 3:15-cv-08132 (D.N.J.). On information and belief, Qilu Ltd. has also affirmatively invoked this Court's jurisdiction by asserting counterclaims in cases that it has litigated in New Jersey. For example, Qilu Ltd. asserted counterclaims in the cases listed above.

16. Qilu Ltd. likewise did not contest personal jurisdiction or venue in cases brought against Qilu Ltd. which was also based on Qilu's filing of ANDA No. 219350. *See, e.g.*, *Eli Lilly & Co., et al., v. Qilu Pharma. Co., Ltd., et al.*, Nos. 2:24-cv-05847 & 2:24-cv-10802 (D.N.J.).

17. Venue is proper in this Court as to Qilu Inc. because, among other things, on information and belief, Qilu Inc. has an active business entity ID in the State of New Jersey (0400704255) with a regular and established place of business at 108 Carnegie Ctr., Suite 208, Princeton, NJ 08540. On information and belief, based on Qilu Inc.'s presence in and connections to New Jersey, discoverable information in Qilu Inc.'s possession, custody, or control regarding the Qilu ANDA will likely show that Qilu Inc. engaged in activities in New Jersey relevant to the preparation or submission of the Qilu ANDA.

18. Qilu Inc. has been sued in this district previously in Hatch-Waxman patent infringement disputes and has not contested personal jurisdiction or venue in one or more cases. *See, e.g.*, *Boehringer Ingelheim Pharms. Inc. v. Qilu Pharm. Co. Ltd., et al.*, No. 3:21-cv-01732 (D.N.J.); *Helsinn Healthcare S.A. et al. v. Qilu Pharm. Co., Ltd. et al.*, No. 3:15-cv-08132 (D.N.J.). On information and belief, Qilu Inc. has also affirmatively invoked this Court's jurisdiction by asserting counterclaims in cases that it has litigated in New Jersey. For example, Qilu Inc. asserted counterclaims in the cases listed above.

19. Qilu Inc. likewise did not contest personal jurisdiction or venue in cases brought against Qilu Inc. which was also based on Qilu's filing of ANDA No. 219350. *See, e.g.*, *Eli Lilly & Co., et al., v. Qilu Pharma. Co., Ltd., et al.*, Nos. 2:24-cv-05847 & 2:24-cv-10802 (D.N.J.).

20. Venue is further proper in this Court as to Qilu because, among other things, Qilu has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the asserted patent that will lead to foreseeable harm and injury to Plaintiffs by filing the Qilu ANDA with the intention of seeking to market the Qilu ANDA Products nationwide,

including within the State of New Jersey. *See* 28 U.S.C. § 1400(b).

PERSONAL JURISDICTION OVER QILU LTD.

21. Plaintiffs reallege paragraphs 1–20 as if fully set forth herein.

22. On information and belief, Qilu Ltd. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

23. This Court has personal jurisdiction over Qilu Ltd. because, *inter alia*, Qilu Ltd., on information and belief, intends to market, sell, and/or distribute the Qilu ANDA Products to residents of this State upon approval of the Qilu ANDA, either directly or through at least one of its partners or wholly-owned subsidiaries or agents, including Qilu Inc. Qilu Ltd.'s intent to sell its ANDA Product here is sufficient to support a finding of specific personal jurisdiction. *See Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755, 762–63 (Fed. Cir. 2016). Qilu Ltd. further makes its generic drug products available in this State and enjoys substantial income from sales of its generic pharmaceutical products in this State.

24. Additionally, on information and belief, Qilu Ltd. has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, *Boehringer Ingelheim Pharms. Inc. v. Qilu Pharm. Co. Ltd., et al.*, No. 3:21-cv-01732 (D.N.J.); *Helsinn Healthcare S.A. et al. v. Qilu Pharm. Co., Ltd. et al.*, No. 3:15-cv-08132 (D.N.J.). Moreover, Qilu Ltd. also consented to personal jurisdiction and venue in cases naming Qilu Ltd. as defendant which were also based on Qilu's filing of ANDA No. 219350. *See, e.g.*, *Eli Lilly & Co., et al., v. Qilu Pharma. Co., Ltd., et al.*, Nos. 2:24-cv-05847 & 2:24-cv-10802 (D.N.J.).

25. Alternatively, to the extent the above facts do not establish personal jurisdiction over Qilu Ltd., this Court may exercise jurisdiction over Qilu Ltd. under Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiffs' claim arises under federal law; (b) Qilu Ltd. would be a

foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Qilu Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and filing ANDAs with the FDA, marketing its drug product candidates, and manufacturing generic pharmaceutical products that will be distributed throughout the United States, such that this Court's exercise of jurisdiction over Qilu Ltd. satisfies due process, and is consistent with the United States Constitution and Laws.

26. Upon information and belief, if the Qilu ANDA is approved, the Qilu ANDA Products will be marketed and distributed by Qilu Ltd., either directly or through at least one of its partners or wholly-owned subsidiaries or agents, including Qilu Inc., in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey.

PERSONAL JURISDICTION OVER QILU INC.

27. Plaintiffs reallege paragraphs 1–26 as if fully set forth herein.

28. On information and belief, Qilu Inc. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

29. This Court has personal jurisdiction over Qilu Inc. because, *inter alia*, Qilu Inc., on information and belief: (1) maintains an active business entity ID, as well as a regular and established place of business, in the State of New Jersey; (2) intends to market, sell, or distribute the Qilu ANDA Products to residents of this State; (3) makes its generic drug products available in this State; and (4) enjoys substantial income from its generic pharmaceutical products in this State.

30. Additionally, on information and belief, Qilu Inc. has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, *Boehringer Ingelheim Pharms. Inc. v. Qilu Pharm. Co. Ltd., et al.*, No. 3:21-cv-01732 (D.N.J.); *Helsinn Healthcare S.A. et al. v. Qilu*

Pharm. Co., Ltd. et al., No. 3:15-cv-08132 (D.N.J.). Moreover, Qilu Inc. also consented to personal jurisdiction and venue in cases naming Qilu Inc. as defendant which were also based on Qilu's filing of ANDA No. 219350. *See, e.g.*, *Eli Lilly & Co., et al., v. Qilu Pharma. Co., Ltd., et al.*, Nos. 2:24-cv-05847 & 2:24-cv-10802 (D.N.J.).

31. Upon information and belief, if the Qilu ANDA is approved, the Qilu ANDA Products will be marketed and distributed by Qilu Ltd., either directly or through at least one of its partners or wholly-owned subsidiaries or agents, including Qilu Inc., in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey.

BACKGROUND

U.S. PATENT NO. 12,257,246

32. On March 25, 2025, the United States Patent & Trademark Office ("USPTO") duly and legally issued United States Patent No. 12,257,246 ("the '246 patent") titled "Composition of 2,4,6-trifluoro-N-[6-(1-methyl-piperidin-4-carbonyl)-pyridin-2-yl[-benzamide." The inventors of the patented invention are Alison Pilgrim, James F. White, Nadia M. J. Rupniak. A true and correct copy of the '246 patent is attached as Exhibit 1. The '246 patent is assigned to CoLucid Pharmaceuticals, Inc., a wholly owned subsidiary of Lilly.

REYVOW®

33. Lilly is the holder of New Drug Application ("NDA") No. 211280 for lasmiditan, for oral use, in 50 mg and 100 mg dosages, which is sold under the tradename REYVOW®. REYVOW® is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations database ("Orange Book") as having New Chemical Entity Exclusivity until January 31, 2025.

34. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '246 patent is

among the patents listed in the Orange Book with respect to REYVOW®.

35. The ’246 patent covers the REYVOW® product and its use.

Prior Actions Related to ANDA No. 219350

36. On March 21, 2024, Qilu sent Lilly a Paragraph IV letter in support of ANDA No. 219350 pertaining to U.S. Patent No. 11,053,214 (“the ’214 patent”). The ’214 patent covers the REYVOW® product and is assigned to CoLucid, a wholly owned subsidiary of Lilly. Lilly and CoLucid filed a complaint for patent infringement with respect to Qilu’s conduct on May 3, 2024. *See Eli Lilly & Co., et al., v. Qilu Pharma. Co., Ltd., et al.*, No. 2:24-cv-05847 (D.N.J.).

37. On August 27, 2024, the USPTO duly and legally issued U.S. Patent No. 12,071,423 (“the ’423 patent). The ’423 patent also covers the REYVOW® product and is assigned to CoLucid. On November 11, 2024, Qilu sent Lilly a Paragraph IV letter in support of ANDA No. 219350 pertaining to the ’423 patent. Lilly and CoLucid filed a complaint for patent infringement with respect to Qilu’s conduct on November 27, 2024. *See Eli Lilly & Co., et al., v. Qilu Pharma. Co., Ltd., et al.*, No. 2:24-cv-10802 (D.N.J.).

38. On December 17, 2024, the parties jointly sought the Court’s permission to consolidate *Eli Lilly & Company, et al. v. Qilu Pharmaceutical Co., Ltd., et al*. Nos. 2:24-cv-05847 & 2:24-cv-10802. Having found good cause, pursuant to Federal Rule of Civil Procedure 42, the Court ordered that Civil Action Nos. 24-05847 and 24-10802 (the “Consolidated Actions”) be consolidated for all purposes, including discovery, case management, and trial, subject to further order of the Court. *Eli Lilly & Company, et al. v. Qilu Pharmaceutical Co., Ltd., et al*. No. 2:24-05847, Docket No. 35; *Eli Lilly & Company, et al. v. Qilu Pharmaceutical Co., Ltd., et al*. No. 2:24-cv-10802, Docket No. 13.

39. Because the ’246 patent did not issue until March 25, 2025, it was not included in the Consolidated Actions. On April 28, 2025, Plaintiffs notified Qilu that the ’246 patent had been

listed in the Orange Book. On May 15, 2025, the parties jointly sought to extend deadlines in the Consolidated Actions to accommodate the '246 patent as part of the existing schedule, which was granted. *Eli Lilly & Company, et al. v. Qilu Pharmaceutical Co., Ltd., et al*. No. 2:24-05847, Docket No. 61.

ACTS GIVING RISE TO THE ACTION

40. Provided here as an exemplary claim, claim 1 of the '246 patent recites:

> 1. A method for the acute treatment of migraine in a human subject in need thereof consisting of oral administration to said subject a pharmaceutical composition adapted for oral delivery, the composition comprising 50 to 200 mg of 2,4,6-trifluoro-N-[6-(1-methyl-piperidin-4-ylcarbonyl)-pyridin-2-yl]-benzamide, or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable diluent or carrier, wherein said composition is administered up to 200 mg daily.

41. On information and belief, Qilu's ANDA reveals that when offered for sale, sold, and/or imported the Qilu ANDA Products comprise 50 to 200 mg of 2,4,6-trifluoro-N-[6-(1-methyl-piperidin-4-ylcarbonyl)-pyridin-2-yl]-benzamide, or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable diluent or carrier.

42. On information and belief, [redacted].

43. On information and belief, Qilu's ANDA seeks approval for human use of the Qilu ANDA Products. Additionally, on information and belief, [redacted].

44. On information and belief, under the direction and control of Qilu, [redacted]

45. On information and belief, [redacted].

46. Therefore, on information and belief, the Qilu ANDA Products when used as directed would be used in a manner that would infringe claims of the '246 patent, including claim 1.

47. On information and belief, Qilu seeks FDA approval for the Qilu ANDA Products, which include method of treatment instructions that would encourage and instruct a healthcare provider to infringe claims of the '246 patent, including claim 1.

COUNT I—INFRINGEMENT OF THE '246 PATENT

48. Plaintiffs reallege paragraphs 1–47 as if fully set forth herein.

49. On information and belief, Qilu submitted the Qilu ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Qilu ANDA Products.

50. Qilu has represented that the Qilu ANDA refers to and relies upon the REYVOW® NDA, and contains data that, according to Qilu, demonstrates the bioavailability or bioequivalence of the Qilu ANDA Products to REYVOW®. Qilu has also represented to the FDA that the Qilu ANDA Products would have the same method of administration and dosage form as REYVOW®.

51. On May 29, 2025, counsel for Plaintiffs received a letter from Qilu (dated May 29, 2025) stating that Qilu had included a certification in the Qilu ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '246 patent are either invalid or will not be infringed by the commercial manufacture, use, sale, offer to sell or importation into the United States of the Qilu ANDA Products (the "Qilu Paragraph IV Certification"). Qilu intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Qilu ANDA Products prior to the expiration of the '246 patent.

52. Under the Hatch-Waxman Act, an owner of a patented drug must file an action in federal court within 45 days of receiving a Paragraph IV letter ("45-day window") to receive certain

benefits under the Act, including a stay of approval of the generic drug for 30 months during the pendency of litigation, as appropriate. 21 U.S.C. § 355 (c)(3)(c).

53. On information and belief, Qilu has infringed at least one claim of the '246 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Qilu ANDA—which, on information and belief, instructs Qilu ANDA Products to be used in a manner as the claimed method of treatment, literally or under the doctrine of equivalents—by which Qilu seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Qilu ANDA Products prior to the expiration of the '246 patent. *See Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1278 (Fed. Cir. 2013).

54. Qilu has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Qilu ANDA Products if the FDA approves the Qilu ANDA. Accordingly, an actual and immediate controversy exists regarding Qilu's infringement of the '246 patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

55. Qilu's manufacture, use, offer to sell, or sale of the Qilu ANDA Products in the United States or importation of the Qilu ANDA Products into the United States during the term of the '246 patent would further infringe, literally or under the doctrine of equivalents, at least one claim of the '246 patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

56. On information and belief, the Qilu ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '246 patent either literally or under the doctrine of equivalents.

57. On information and belief, the use of the Qilu ANDA Products constitutes a material part of at least one of the claims of the '246 patent; Qilu knows that the Qilu ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '246 patent, either literally or under the doctrine of equivalents; and the Qilu ANDA Products are not a staple article of

commerce or commodity of commerce suitable for substantial non-infringing use.

58. On information and belief, the offering to sell, sale, and/or importation of the Qilu ANDA Products would contributorily infringe at least one of the claims of the ’246 patent, either literally or under the doctrine of equivalents.

59. On information and belief, Qilu had knowledge of the ’246 patent and, by its promotional activities, proposed prescribing information, and/or package inserts for the Qilu ANDA Products, knows or should know that they will aid and abet another’s direct infringement of at least one of the claims of the ’246 patent, either literally or under the doctrine of equivalents.

60. On information and belief, the offering to sell, sale, and/or importation of the Qilu ANDA Products by Qilu would actively induce infringement of at least one of the claims of the ’246 patent, either literally or under the doctrine of equivalents.

61. On information and belief, Qilu does not deny that use of the Qilu ANDA Products will infringe at least one of the claims of the ’246 patent and in the Qilu Paragraph IV Certification, Qilu did not deny that use of the Qilu ANDA Products will infringe claims of the ’246 patent.

62. Plaintiffs will be substantially and irreparably harmed if Qilu is not enjoined from infringing the ’246 patent.

63. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs’ reasonable attorney fees.

64. On information and belief, based on the information provided by Qilu to date, the factual contentions in paragraph 40–63 have evidentiary support. On information and belief, the factual contentions in paragraphs 40–63 will have further evidentiary support following a reasonable opportunity for further investigation or discovery.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment against Qilu

and for the following relief:

a. A Judgment be entered that Qilu has infringed at least one claim of the ’246 patent by submitting the Qilu ANDA;

b. A Judgment be entered that this case is exceptional, and that Plaintiffs are entitled to their reasonable attorneys’ fees pursuant to 35 U.S.C. § 285;

c. That Qilu, its officers, agents, partners, servants, employees, and those persons acting in active concert or participation with all or any of them be preliminarily and permanently enjoined from: (i) engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs or methods of administering drugs claimed in the ’246 patent, and (ii) seeking, obtaining or maintaining approval of ANDAs until the expiration of the ’246 patent or such other later time as the Court may determine;

d. A Judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Qilu’s ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration date of the ’246 patent, including any extensions;

e. That Plaintiffs be awarded monetary relief if Qilu commercially uses, offers to sell, or sells its respective proposed generic versions of REYVOW® or any other product that infringes or induces or contributes to the infringement of the ’246 patent, within the United States, prior to the expiration of those patents, including any extensions, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest;

f. Costs and expenses in this action; and

g. Such other and further relief as the Court deems just and appropriate.

Dated: June 30, 2025

Respectfully submitted,

/s/ Liza M. Walsh
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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

I hereby certify that, to the best of my knowledge, the matter in controversy is related to the following actions:

- *Eli Lilly & Company, et al. v. Qilu Pharmaceutical Co., Ltd., et al*. Nos. 2:24-cv-05847 & 2:24-cv-10802 (EP-JSA) (consolidated), pending before the United States District Court for the District of New Jersey, in which Plaintiffs asserted claims of patent infringement against Qilu in connection with Qilu's submission of ANDA No. 219350; and
- *Eli Lilly & Company, et al. v. Humanwell Pharmaceutical US, Inc., et al.*, No. 2:25-cv-2020 (EP-JSA), pending before the United States District Court for the District of New Jersey, in which Plaintiffs asserted claims of patent infringement against Humanwell Pharmaceuticals US, Inc. and Epic Pharma, LLC, in connection with Humanwell's submission of ANDA No. 219669.

Dated: June 30, 2025

Respectfully submitted,

/s/ Liza M. Walsh

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LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

Dated: June 30, 2025

Respectfully submitted,

/s/ Liza M. Walsh

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